EIP

Uncertainty remains over medical device SPCs in Europe

The UK Intellectual Property Office has refused to grant an SPC for a medical device, as noted in the decision BL O/141/14. Whilst those aware of the SPC legislation may not find this surprising, a small number of other European jurisdictions have taken a different view and have granted SPCs for medical devices.

A supplementary protection certificate ("SPC") is a form of compensation by which an extra period of monopoly is granted at the end of a patent's life, as recompense for the period of the patent's monopoly during which the patent holder cannot market a product protected by the patent due to the need to first obtain regulatory approval for that product. SPCs can be obtained for medicinal products and plant protection products.

An SPC for a medicinal product requires that a valid authorisation to place the product on the market has been granted in accordance with Directives 2001/83/EC or 2001/82/EC (Article 3(b) of Regulation (EC) No 469/2009, the "SPC Regulation"). These Directives relate primarily to medicines, although some medical devices are regulated under Directive 2001/83/EC (e.g. pre-filled syringes, anti-microbial wound dressings where primary action is drug delivery and other specifically pre-charged products). In theory, an authorisation for a medical device under one of these Directives could form the basis for an SPC; however, it is also a requirement that the authorisation relied upon is the first authorisation to put the active ingredient on the market, and this is generally not the case for authorisations for such pre-charged products.

Where the drug effect is ancillary, and device functionality is primarily by physical means, then instead Directive 93/42/EEC or 90/385/EEC will apply (for example, drug delivery devices of general application, specifically coated catheters, anti-microbial wound

dressings where primary action is wound dressing, etc.). As these directives are not specified in the SPC Regulation it might be assumed that devices authorised under these
p2 directives will not be eligible for SPCs. However, the SPC legislation requires an authorisation "in accordance with Directive 2001/83/EC", and there have been rulings in some countries which have held that the regimes under Directive 93/42/EEC or 90/385/EEC are sufficiently similar to Directives 2001/83/EC or 2001/82/EC for authorisations under Directive 93/42/EEC or 90/385/EEC to be in accordance with Directives 2001/83/EC or 2001/82/EC.

Specifically, both Germany and the Netherlands have awarded SPCs on the basis of authorisations under Directive 93/42/EEC or 90/385/EEC. In the German decision in relation to SPC application 12 2005 000 052 (14 W (pat) 12/07), the German court upheld an SPC for a microsphere comprising yttrium-89, activated into ytrrium-90 in situ. It was determinative that the product comprised an active which had to be authorised under 90/385/EEC as it was combined with a device but if separate would have been authorised under 2001/83/EC. The equivalent SPC was also allowed in the Netherlands but refused in at least Belgium, Denmark, Italy and Sweden. A similar decision in the Netherlands was made for replacement joint fluid under 93/42/EEC (Rechtsbank's-Gravenhage, AWB 02/1729 OCT).

Prior to this recent decision, the position in the UK was unclear, with the UKIPO SPC Guide for Applicants merely stating that such an SPC was "Possibly" allowable.

There has now been some guidance on this, in decision BL O/141/14. Here, an SPC had been applied for in relation to a "Platelet preparation obtainable by addition, and subsequent photoactivation, of amotosalen or its salt, to a suspension of platelets in plasma", for which an authorisation under Directive 93/42/EEC had been obtained. It was argued that this authorisation was equivalent to one under Directive 2001/83/EC as the device contained a substance which if used separately would have required authorisation under Directive 2001/83/EC, and, further, because this authorisation was for a Class III medical device, which required the highest standard of medical device assessment, including verification of the safety, quality and usefulness of the substance. However, after a detailed assessment of the different requirements for authorisation under the two Directives, the Hearing Officer concluded that the two processes were not the same, and so refused the application for an SPC on the basis that there was no authorisation in accordance with Directive 2001/83/EC or Directive 2001/82/EC.

This decision may yet be appealed, although at present it does seem likely that the UK will adopt the majority view of European countries in refusing SPCs for devices authorised under Directive 93/42/EEC or 90/385/EEC. Nevertheless, the fact there is

some divergence between European territories means yet another reference to the CJEU concerning SPCs cannot be ruled out.

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